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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,822	10/24/2005	Mark Brister	PA1187	3938
	7590 03/09/2007 VASCULAR, INC.		EXAMINER	
IP LEGAL DEP	PARTMENT		ADAMS, AMANDA S	
3576 UNOCAL SANTA ROSA,		,	ART UNIT	PAPER NUMBER
•	,		3731	
	•			
SHORTENED STATUTORY	PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/09/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

		Application No.	Applicant(s)			
Office Action Summary		10/531,822	BRISTER, MARK			
		Examiner	Art Unit			
	·	Amanda Adams	3731			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS OF time may be available under the provisions of 37 CFR 1.15 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	L. sely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1) 🏹	Responsive to communication(s) filed on <u>08 Fe</u>	ebruary 2007.				
	This action is FINAL . 2b)⊠ This action is non-final.					
· <u> </u>	,—					
•=	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	ion of Claims					
4)⊠	Claim(s) <u>1-125</u> is/are pending in the application	1.				
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)🛛	6)⊠ Claim(s) <u>1-25</u> is/are rejected.					
7)	Claim(s) is/are objected to.		•			
. 8)□	Claim(s) are subject to restriction and/or	r election requirement.				
Applicati	ion Papers					
9)[The specification is objected to by the Examine	r. ·				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority ι	under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received.						
1. Certified copies of the priority documents have been received.2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachmen	t(s)					
_	e of References Cited (PTO-892)	4) Interview Summary	(PTO-413)			
2) Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ite			
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:						

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 1, 3-6, 8-11, 13, 14, 17, 18, and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Tedeschi (US 20030204238).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

3. Regarding **claims 1, 6, and 22**, Tedeschi discloses the invention substantially as claimed comprising a catheter delivery system (par. 22), a stent with a first and second discrete region (par. 34), a first coating section disposed on the first region and comprising a first polymer, and a second coating section disposed on the second region and comprising a second polymer (par. 34).

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4. Regarding **claims 3, 4, 8, and 9,** Tedeschi discloses that the first coating section includes a first therapeutic agent and that the second coating section includes a second therapeutic agent (par. 23 and 28).

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- 5. Regarding **claims 5 and 10**, Tedeschi discloses that the first and second regions form a striped ring pattern (fig. 2 [218] and [216] form banded regions).
- 6. Regarding **claims 11 and 18**, Tedeschi discloses the method substantially as claimed including the stent with first and second regions as disclosed above, mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (par. 23), applying the first polymer solution to the first region to form a first coating section (par. 27) and also performing these steps for the second polymer, second therapeutic agent, and second region (par. 27).
- 7. Regarding **claims 13 and 20**, Tedeschi discloses curing the first and second polymer solutions (par. 32).
- 8. Regarding claims **14**, **17**, **and 21**, Tedeschi discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (par. 27).
- 9. Claims 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al (US 6,616,765).
- 10. Castro discloses a stent with a first discrete region and a second discrete region (fig. 13A-13H), a first polymer including a first therapeutic agent, the first polymer disposed on the discrete first region, and a second polymer including a second therapeutic agent, the second polymer disposed on the discrete second region (col. 17,

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line 60 – col. 18, line 3). Castro also discloses that the first and second discrete regions are separated by a bare section (fig. 13F).

Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. Claims 11-21, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (US 6,616,765).
- 13. **Regarding claims 11 and 18**, Castro discloses the invention substantially as claimed above, further disclosing mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (col. 11, lines 7-13), applying the first polymer solution to the first region to form a first coating section (col. 14, lines 65-67), mixing a second polymer and second therapeutic agent with a solvent to form a second polymer solution (col. 17, line 62 col. 18, line 4), and applying the second polymer solution to the second region to form a second coating section (col. 18, lines 14-32). Castro fails to specifically disclose that the solvent mixed with the second polymer and second therapeutic agent is a second solvent, but teaches that it could be a second solvent (col. 11, lines 55-59; col. 12, lines 20-24). Choosing a solvent based on the

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polymer chosen implies that if a second polymer is used, then a second solvent will also be used. Further, Castro discloses that all other variables of the second composition are different than that of the first, so it would have been obvious to choose a second solvent when forming the second polymer solution.

- 14. **Regarding claims 12 and 19**, Castro further discloses the first and second polymer solutions may be applied simultaneously (col. 17, lines 61-64).
- 15. **Regarding claims 13 and 20**, Castro discloses curing the first and second polymer solutions (col. 9, lines 64-65).
- 16. **Regarding claims 14 and 21**, Castro further discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (col. 6, lines 24-35).
- 17. **Regarding claims 15-17**, Castro further discloses mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45).
- 18. **Regarding claims 24 and 25**, Castro discloses the invention substantially as claimed above. However, due to lack of criticality in the applicant's specification, the distances between discrete coated regions serve no particular purpose and provide no additional benefit as opposed to any other specific distances. Therefore, it would have been obvious to arbitrarily choose these distances because they are both within the scope of the size of an intravascular stent.

Response to Arguments

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19. Applicant's arguments with respect to claims 1, 3-6, 8-11, 13, 14, 17, 18, and 20-22 filed on 2/8/2007 have been fully considered but they are not persuasive.

- 20. Tedeschi does disclose the invention substantially as claimed above. The limitations of Applicant's claims require that the first and second regions of the stent are discrete. However, the first and second coating sections, which is where the polymers are disposed, do not have to be discrete from each other. Therefore Tedeschi still meets the limitations of these claims. Also, the coating sections do not have to be disposed directly onto the stent, as the claim limitations only necessitate that the coating sections must be disposed on the regions. The coating sections do not have to be discrete as explained above, therefore it is okay for the coating sections to overlap each other.
- 21. Applicant's arguments with respect to the rejection(s) of claim(s) 12, 19, and 23-25 under 35 USC 102(e)/103 have been fully considered and are persuasive.

 Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Castro et al (US 6,616,765).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA

GLENN K. DAWSON PRIMARY EXAMINER